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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|---------------|----------------------|-------------------------|------------------|
| 10/621,667 | 07/17/2003 | Sarah Rose Hertel | 129491 | 2051 |
| 75 | 90 12/01/2006 | | EXAM | INER |
| Dean D. Small | | | KISH, JAMES M | |
| Armstrong Teasdale LLP Suite 2600 | | | ART UNIT | PAPER NUMBER |
| One Metropolitan Square | | | 3737 | |
| St. Louis, MO | 63102 | | DATE MAILED: 12/01/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|---|--|--|--|--|
| Office Antique Comments | 10/621,667 | HERTEL ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | James Kish | 3737 | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the o | correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e. cause the application to become ABANDONE | N. nely filed I the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | •• | | | | |
| 24)24 | s action is non-final. | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1,2,4-12,15-18,20,22,23 and 25 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) <u>1,2,4-12,15-18,20,22,23 and 25</u> is/are rejected. | | | | | | |
| , | 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| 8)[are subject to restriction and | or election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | _ | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | | Patent Application | | | | |

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DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 18, 2006 have been fully considered but they are not persuasive.

- 1. Applicant argues that neither Townsend et al. (US Patent No. 6,490,476) nor Kaufman et al. (US Patent No. 5,971,767) describe or suggest identifying a ROI in a fused volume by distinguishing the density of that region. Examiner respectfully disagrees. Kaufman describes a assigning opacity coefficients to each voxel within the images. "A high density scanned voxel will indicate either a wall or other dense matter besides simply open space. An operator or program routine could then change the opacity coefficient of a voxel or group of voxels to make them appear transparent or semi-transparent", thereby defining a region of interest. See column 13, lines 14-52. Also see column 2, lines 54-55 where it is stated, "defining the portion of the organ which is to be examined..."
- 2. Applicant also argues that neither Townsend nor Kaufman describe or suggest a program configured to make certain determinations prior to fusing images from CT and PET scans. Figure 3 displays a control window for the CT/PET fusing device, therefore providing a program. It is inherent that the computer would perform a determination before fusing the CT image with the PET image. Before either image could be fused with the other, the computer would need to load the images from a stored location, whether remotely or on that computer's hard drive. The program would determine

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whether or not the scans had been performed depending on whether or not the files are found.

3. Applicant also argues that neither Townsend nor Kaufman describe or suggest determining whether the colon is inflated with at least one of gas and air. Kaufman provides a step in preparing the colon to be scanned in order to be viewed for examination if required by either the doctor or the particular scanning instrument (column 4, lines 23-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-2, 4-12, 15-18, 20, 22-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al. (US Patent No. 6,490,764) in view of Kaufman et al. (US Patent No. 5,971,767). Townsend discloses a combined PET and X-ray CT tomography device for imaging of any organ in any part of the body (column 9, line 65 through column 10, line 3). The device can then fuse the images together (column 2, lines 63-67). A display is included to display the 3-D volume data set. The 3D display computer provides the user with the ability to explore the functional anatomy of the human body fully in three dimensions (column 14, lines 31-43). While Townsend

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does not describe in detail the use of the device for preparation and imaging of the colon. Kaufman teaches a system and method for generating a 3D visualization image such as an organ and exploring the image using a guided navigation system which allows the operator to travel along a flight path and to adjust the view to a particular portion of the image of interest in order, for example, to identify polyps, cysts or other abnormal features in the visualized organ (column 2, lines 36-44 and Abstract). The predefined flight plan is based on a centerline of the organ of interest (column 3, lines 12-14 and column 6, lines 23-25). As can be seen from Figure 1, the first step (101) is to prepare the organ, if necessary, for the imaging procedure. In the case of the colon, air or CO₂ can be forced into the colon (column 4, lines 23-34). In step 103-105 the object is scanned, converted to 3D and then the operator can select a particular portion of the organ to examine. The physician can view a 2D slice overview map to indicate the section to be examined (column 5, lines 24-25). See column 5, lines 34-60 for descriptions of steps 107 and 109 of Figure 1. Also see column 6, lines 26-31. See Figure 14 and column 14, lines 21-67 for detailed descriptions of the system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the dual imaging modality system of Townsend in place of a single imaging modality as disclosed by Kaufman because PET has the ability to add unique functional information to the images obtained by conventional anatomical-based modalities, such as CT, and PET allows discrimination of benign from malignant causes of lesions (column 1, lines 27-44).

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With respect to claim 4, even thought the flight plan is predefined, the operator can manually override the "auto-pilot" feature and navigate the "camera" to any desired location within the 3D visualization of the organ, as described in Kaufman.

With respect to claim 7, see Figures 2a-b of Townsend.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on $8:30 - 5:00 \sim Mon. - Fri..$

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER